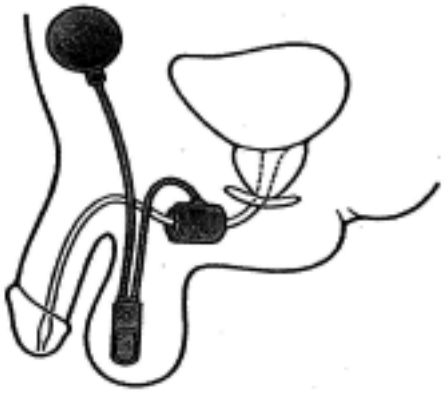
U.S. Food and Drug Administration - Center for Devices and Radiological Health

New Device Approvals

AMS Sphincter 800™ Urinary Prosthesis - P000053



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	AMS Sphincter 800™ Urinary Prosthesis
Manufacturer:	American Medical Systems, Inc.
Address:	10700 Bren Road West, Minnetonka, Minnesota 55343
Approval Date:	June 14, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000053a.pdf

What is it? The AMS Sphincter 800™ Urinary Prosthesis is an implanted device designed to allow patients who have incontinence (loss of urinary control) due to prostate surgery to control urination. The device consists of a fluid-filled cuff that surrounds the urethra (the tube-shaped organ that carries urine from the bladder to the outside of the body), a pump implanted near the testicles, a balloon implanted in the abdomen, and tubing to connect these parts.

How does it work? The device mimics the function of the urinary sphincter, the muscle that opens and closes the urethra. To urinate, the patient squeezes the pump in the scrotum. This causes fluid to drain from the cuff, which opens the urethra. The cuff automatically refills several minutes later, which closes the urethra.

When is it used? This device is used in men who have severe urinary incontinence because of prostate surgery.

What will it accomplish? Approximately 90% of patients who receive these implants reported being dry or having little urine leakage (1-3 pads a day). Side effects are infrequent, and consist of infection, wearing away of the tissue next to the device, pain, movement of the device within the body, mechanical problems with the device, and the return of incontinence. Approximately 20% of patients will need to have their devices surgically replaced within the first 2 years.

When should it not be used?

This treatment should not be used in patients who:

- cannot have surgery,
- have abnormal bladder contractions or obstruction of the urethra,

- do not have the strength or ability to pump the device.

Additional information: The SSED and Labeling will be available at: http://www.fda.gov/cdrh/pdf/p000053.html

(Updated 7/19/2001)